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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,283	07/15/2005	Hans-Ulrich Petereit	273014US0PCT	5271

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
02/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/542,283	PETEREIT ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4 and 8-9, drawn to a method for producing an oral pharmaceutical form with immediate disintegration and active ingredient release even in the mouth.

Group II, claim(s) 5-7 and 10-11, drawn to an active ingredient containing powder.

As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions." Moreover, as stated in Rule 13.2 PCT, Unity of Invention is satisfied "where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art so linked as to form a single general inventive concept." The examiner respectfully submits that, as presented,

instant composition claims 5-7 and 10-11 do not present a contribution over the prior art. As disclosed in US 5,158,777, the composition claims 5-7 and 10-11 are anticipated by the prior art (Examples 1 and 3 which disclose a tablet containing ascorbic acid, methacrylic acid copolymer (EUDRAGIT®) and stearic acid). As a result, as currently presented, the instant composition claims do not share a special technical feature with the instant method claims 1-4 and 8-9 and, as such, unity between the above Groups I – II is broken.

2. The inventions listed as Groups I – II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is a method for producing an oral pharmaceutical form with immediate disintegration. The technical feature of Group II is an active ingredient containing powder. Group I is drawn to a method for producing a product whereas group II is drawn to a product. As such, Group I and Group II do not share the same special technical feature. Therefore, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Election of Species

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

4. The following is a list of anionic active ingredients as set forth in claims 1, 5, and 6: Anionic analgesic, anionic antirheumatic and anionic antibiotic

If applicant selects Group I, or II, one species from the anionic active ingredients group (claims 1, 5, and 6) must be chosen to be fully responsive.

The claims are deemed to correspond to the species listed above in the following manner: Anionic analgesic, anionic antirheumatic and anionic antibiotic are species of a generic category, anionic active pharmaceutical ingredients.

The following claim(s) are generic: claims 1, 5 and 6.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Anionic analgesics, anionic antirheumatics and anionic antibiotics are chemically and structurally distinct chemical entities.

5. Upon election of a species of an anionic active ingredient (anionic analgesics, anionic antirheumatics and anionic antibiotics), applicant is required to further elect a corresponding anionic active pharmaceutical ingredient.

The following is a list of anionic active pharmaceutical ingredients as set forth in claim 7:

acamprosate, aceclofenac, acemetacin, acetylcysteine, acetylsalicylic acid, acetyltyrosine, acipimox, acitretin, alanine, alendronic acid, amethopterin, amino acids, amoxicillin, ampicillin, ascorbic acid, atorvastatin, azidocillin, aztreonam, bacampicillin, baclofen, benazepril, bendamustine, benzylpenicillin, bezafibrate, biotin, bornaprine,

bumetanide, cabastine, canrenoic acid, carbamoylphenoxyacetic acid, carbidopa, carbimazole, carbocisteine, carisoprodol, cefaclor, cefadroxil, cefalexin, cefazolin, cefepime, cefetamet, cefixime, cefotaxime, cefotiam, cefoxitin, cefpodoxime, ceflazidime, ceflibuten, ceftriaxone, cefuroxime, cetirizine, chenodeoxycholic acid, chlorambucil, cidofovir, cilastatin, cilazapril, cinoxacin, ciprofloxacin, cisatracurium besilate, clavulanic acid, clodronic acid, clorazepate, cromoglicic acid, desmeninol, diclofenac, dicloxacillin, enoxacin, eprosartan, etacrynic acid, etidronic acid, etofylline, etomidate, felbinac, felodipine, fenofibrate, fexofenadine, flavoxate, fleroxacin, flucloxacillin, flufenamic acid, flumazenil, flupirtine, flurbiprofen, fluvastatin, fosfomycin, fosinopril, furosemide, fusidic acid, gabapentine, gemfibrozil, ibandronic acid, ibuprofen, iloprost, imidapril, imipenem, indomethacin, irinotecan, isradipine, ketoprofen, lercanidipine, levodopa, levofloxacin, liothyronine, lipoic acid, lisinopril, lodoxamide, lomefloxacin, lonazolac, loracarbef, loratadine, lovastatin, mefenamic acid, meropenem, mesalazine, metamizole, methotrexate, methyldopa, mezlocillin, moexipril, montelukast, moxifloxacin, mupirocin, naproxen, natamycin, nateglinide, nedocromil, nicotinic acid, nifedipine, nilvadipine, nimodipine, nisoldipine, nitrendipine, norfloxacin, ofloxacin, olsalazine, orotic acid, oxacillin, pamidronic acid, pangamic acid, penicillamine, phenoxymethylpenicillin, pentosan polysulfate, perindopril, pethidine, pipemidic acid, piperacillin, pirenoxine, piretanide, probenecid, proglumide, propicillin, prostaglandins, quinapril, quinaprilate, ramipril, repaglinide, reserpine, risedronic acid, salicylic acid, sulfasalazine, spirapril, sulbactam, sulfasalazine, sultamicillin, tazarotene, tazobactam, telmisartan, tiagabine, tiaprofenic acid, tilidine, tiludronic acid, trandolapril, tranexamic

acid, valproic acid, vigabatrine, vincamine, vinpocetine, zanamivir, zoledronic acid, zopiclone, salts thereof and isomers thereof.

If applicant selects Group I or II, one species from the anionic active pharmaceutical ingredients group (claim 7) must be chosen to be fully responsive.

The claims are deemed to correspond to the species listed above in the following manner: "acamprosate ... zopiclone" are species of a generic category, anionic active pharmaceutical ingredients.

The following claim(s) are generic: claim 7.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: "acamprosate ... zopiclone" are chemically and structurally distinct chemical entities.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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